

ABRAXANE® in Focus at International Conference



CANCER DRUG ABRAXANE® IN FOCUS AT INTERNATIONAL CONFERENCE

Delegates to hear trial results for future possible ABRAXANE indications including lung cancer and melanoma

Melbourne: 27 May 2010: World leading advanced breast cancer drug ABRAXANE® (nanoparticle albumin-bound paclitaxel) will be in focus at a leading international medical conference in Chicago next week.

Specialised Therapeutics Australia Pty Ltd (STA), which markets the drug in Australia, says its lead product will be showcased in 31 abstracts at the American Society of Clinical Oncology (ASCO) Conference, which begins in Chicago on June 4.

All presentations will highlight interim or final results for trials with ABRAXANE in several types of cancers, including breast, non-small cell lung, melanoma,

ovarian, head and neck, pancreatic and bladder cancer.

Specialised Therapeutics Australia chief executive officer Mr Carlo Montagner said while the drug was currently only approved for metastatic breast cancer, trials around the world into the use of ABRAXANE in other cancer types were “extremely encouraging”.

He indicated Specialised Therapeutics Australia will submit the new data, when available, to the Therapeutic Goods Administration for approval of ABRAXANE in other cancers.

Among ASCO presenters will be world renowned cancer authority Dr Mark Socinski, from the University of North Carolina Lineberger Comprehensive Cancer Centre.

Dr Socinski will present the tumour response rates for the pivotal Phase 3 registration trial of ABRAXANE on 1052 lung cancer patients globally.

The major global study, which included Australian patients, trialled ABRAXANE in combination with Carboplatin, compared with solvent-based paclitaxel and Carboplatin, as a first line therapy in advanced non-small cell lung cancer.

Mr Montagner said he expected strong international interest in this presentation and other ABRAXANE abstracts, with the world’s first nanoparticle drug approved in over 36 countries.

He said that most recently, delegates at the American Association for Cancer Research in Washington were told the drug may have further potential in patients with triple-negative breast cancers when used in combination with Bevacizumab¹.

nab-paclitaxel plus bevacizumab was shown to inhibit tumour growth by 100%, and reduced the incidence of lymph node and lung metastases by 50% and 87% respectively.

Mr Montagner added: “As these pivotal clinical trials around the world advance, we look forward to potentially bringing a new treatment option to patients with these difficult to treat cancers. It may be several years before we have approval for these new indications, however we are extremely encouraged by these results and look forward to presenting them to global medical experts at the ASCO

conference.”

Ends.

About Specialised Therapeutics Australia Pty Ltd

Specialised Therapeutics Australia Pty Ltd (STA) was established to identify, develop and commercialise innovative anti-cancer and other specialised therapies for the Australasian market. ABRAXANE is the first of such therapies. Based in Melbourne, Australia, the privately held company is currently developing several more important therapeutic agents for release in Australia and New Zealand.

About ABRAXANE

In Australia, ABRAXANE is currently approved and reimbursed by the Pharmaceutical Benefits Scheme (PBS) for the treatment of metastatic breast cancer after failure of prior therapy which includes an anthracycline.

ABRAXANE has also been granted orphan drug designation by the Therapeutic Goods Administration for the treatment of pancreatic cancer. Orphan drug status is granted to drugs used to treat relatively rare diseases such as pancreatic cancer and may allow for priority evaluation by the TGA.

ABRAXANE is approved for metastatic breast cancer in over 35 countries including the U.S., Canada, European Union and China, and more than 60,000 cancer patients have received ABRAXANE therapy in the past five years.

Additionally, ABRAXANE is currently under Phase III investigation for the treatment of the following cancers: non-small cell lung, malignant melanoma, and metastatic pancreatic.

ABRAXANE is a solvent-free, nanoparticle chemotherapy treatment option for metastatic breast cancer². Developed using Abraxis BioScience’s proprietary *nab*^(TM) technology platform, ABRAXANE is a nanoparticle protein-bound chemotherapy agent. ABRAXANE combines paclitaxel with albumin, a naturally-occurring human protein, to deliver the drug and eliminate the need for

solvents in the administration process. Nanoparticle technology allows ABRAXANE to deliver a 49% higher dose compared to regular solvent-based paclitaxel without compromising safety and tolerability ^{2,3}.

In a randomised Phase III study of metastatic breast cancer patients, ABRAXANE demonstrated nearly double the overall tumour response rate compared to solvent-based paclitaxel ^{2,3}. Anthracycline pre-treated patients lived significantly longer ⁴.

The tolerability with ABRAXANE and solvent-based paclitaxel was comparable, despite the 49% greater dose of paclitaxel administered as ABRAXANE^{2,3}. Neutropenia was lower with ABRAXANE compared to solvent-based paclitaxel, although there was an increase in incidence of grade 3 peripheral neuropathy with ABRAXANE. However the median time to improvement, from grade 3 peripheral neuropathy to grade 2 or lower, was 22 days. No adverse events were reported that were not already known for paclitaxel^{2,3}.

FOR MORE INFORMATION PLEASE CONTACT EMMA POWER AT MONSOON COMMUNICATIONS ON (03) 9620 3333 OR 0419 149 525.

References:

1 .Ran S et al. Abstract AACR 2010: 3852,

2. Abraxane Product Information

3. Gradishar WJ et al. J Clinical Oncology 2005; 23:7794-7803

4. Vukelja SJ et al. Abstract ASCO 2008;26:1082